

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action. Claims 1, 4-7, 10-11, 14-15, and 17-27 are pending in the present application. Claims 1, 4-7, 10-11, 14-15, and 17-24 have been amended to more particularly point out and distinctly claim the present invention. New claims 25-27 have been added. Support for new claims 25-26 may be found in original claims 8 and 9. Support for new claim 27 may be found generally throughout the specification. Claims 2, 3, 8-9, 12-13, and 16 have been cancelled.

In the outstanding Official Action, the Examiner stated that the amendment to claim 8 in applicant's previous response should have been to claim 9. As a result, the Examiner requested that claims 8 and 9 be cancelled and that the subject matter of those claims be pursued in new claims 25-26. As suggested by the Examiner, claims 8 and 9 have been cancelled and new claims 25-26 have been added to the present application. Applicant would like to thank the Examiner for the suggestion as to how to overcome this objection.

Claims 6 and 10-11 were rejected for allegedly failing to comply with the requirements of 35 USC §101. Applicant believes that the present amendment obviates this rejection.

Claim 6 has been amended to recite an isolated nucleic acid. Claims 10 and 11 are directed to isolated antibodies. As

a result, applicant believes that the claimed nucleotides and antibodies satisfies the requirements of 35 USC §101.

Claims 12-13 and 16-17 were rejected under 35 USC §101 for allegedly being directed to a "use" without reciting any steps involved in a method/process. Applicant believes that the present amendment obviates this rejection.

Claims 12-13 and 16 have been cancelled. Claim 17 has been amended to recite a method of making an immunogenic preparation, comprising adding the protein according to claim 1 to a pharmaceutically and/or veterinary acceptable carrier. Thus, it is believed that claim 17 satisfies the requirements of 35 USC §101.

Claims 1, 5, and 14-15 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In imposing the rejection, the Official Action objected to the term "essentially identical". Claims 1, 5, and 14-15 have been amended so that this term is no longer recited in the claims. Thus, it is believed that claims 1, 5, and 14-15 are definite to one of ordinary skill in the art.

As to claims 2, 12, and 20, the Official Action rejected these claims for reciting the term "such as".

As noted above, claims 2 and 12 have been cancelled. Claim 20 has been amended so that this terminology is no longer recited in the claim. It is believed that claim 20 has been amended in a manner so that it is definite to one of ordinary skill in the art.

Claim 6 was rejected under 35 USC §112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

The outstanding Official Action alleged that the term "stringent conditions" was indefinite. However, while applicant believes that this term is broad, applicant believes that the term is definite to one of ordinary skill in the art. Nevertheless, in the interest of advancing prosecution, the claim has been amended to recite that the stringent conditions would be those in which the salt concentration is less than about 1.0 M Na ion, in a pH of 7.0 to 8.3, and the temperature is at least about 30°C. Thus, it is believed that the claim is definite to one of ordinary skill in the art.

Claim 9 was rejected for reciting the phrase "optionally". The Official Action alleged that it was indefinite as to whether the information that followed the term was part of the claim. However, claim 9 has been cancelled.

Claim 13 was rejected for reciting the term "similar biological activities". Claim 13 has also been cancelled. Thus,

applicant believes that this rejection has been rendered moot by the present amendment.

Claims 14 and 15 were rejected for reciting the term "mimic". Claims 14 and 15 have been amended so that term is no longer recited in the claims.

Thus, in view of the above, it is believed that claims 1, 4-7, 10-11, 14-15, and 17-27 are definite to one of ordinary skill in the art.

Claims 1-24 were rejected under 35 USC §112, first paragraph, for allegedly not complying with the written description requirement. This rejection is respectfully traversed.

Applicant believes that claims 1-24 are fully supported by the present disclosure. The claimed invention relates to a recombinant protein useful in the diagnosis of mite infections in mammals. Claim 1 recites an isolated mite protein comprising at least about 83 amino acids of the sequence disclosed in SEQ ID NO. 2. SEQ ID NO. 2 is directed to 427 amino acids.

While the Official Action alleges that the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus, applicant believes that these distinguishing attributes are sufficiently described in the present specification. Indeed, the specification plainly recites that the present invention relates to isolated antigenic protein, the nucleic acid of the protein and methods involving the protein

and nucleic acid (page 2, line 25 to page 3, line 4). At page 10, line 1, the specification notes that the invention relates to a protein comprised of at least 83 amino acids of SEQ ID NO. 2.

Moreover, the Examiner's attention is directed to the figures and examples provided in the present specification. Figure 1 shows the extent of the recombinant protein according to the invention in relation to the native protein. Figure 2 is directed to the recombinant plasmid used for the expression of the mite protein MSA1 according to the invention. Figure 3 provides an overview of the cloning strategy and Figure 4 shows the results of the Western blot analysis of the mite recombinant protein according to the invention.

As a result, it is believed that the claims directed to an isolated mite protein comprising at least about 83 amino acids of SEQ ID NO. 2 are fully supported by the present disclosure.

Claims 16-21 were rejected under 35 USC §112, first paragraph, for allegedly being based on a non-enabling disclosure. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that the present disclosure was not enabling for vaccines comprising SEQ ID NO. 2.

However, as noted above, claim 16 has been cancelled. As to claims 17-21, claim 17 is directed to a method of making an immunogenic composition. Claims 18-19 are directed to an immunogenic preparation. Moreover, as noted above, the claimed

invention is fully supported by the present disclosure. As a result, applicant believes that the claims are fully enabled.

Claim 8 was rejected under 35 USC §112, first paragraph. The Official Action alleged that the specification was not enabling for all recombinant cells. This rejection is respectfully traversed.

Claim 8 has been cancelled. The subject matter of claim 8 is now recited in claim 25. While the Official Action contends that the present disclosure is not enabling for all recombinant cells, applicant notes that the recombinant cell of claim 25 comprises a vector according to claim 7. Claim 7 in turn recites an expression vector which comprises a nucleic acid which encodes for an isolated mite protein comprising at least about 83 amino acids of the sequence disclosed in SEQ ID NO. 2. Thus, claim 25 is not directed to any or all recombinant cells.

While the Official Action contends that applicant has provided no guidance or working examples of any transformed cell line other than a prokaryotic *E. coli* strain, the Examiner is respectfully reminded that it is a well-founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope for the protection sought must be supported by evidence or reasoning substantiating a doubt so expressed. As a matter of law, the express teaching of the present specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As

stated by the Court of Customs and Patent Appeals in the case of
In re Dinh-Nguyen and Stanhagen, 181 USPQ 46 (CCPA 1974):

"any assertion by the Patent Office that the enabled disclosure is not commensurate in scope for the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. 181 USPQ at 47."

Such a standard must be applied with great care when the conjecture of the Patent Office is contrary to the teachings of the specification. When reviewing the position of the Patent Office on this point, it is apparent that no evidence is adduced and is in any way inconsistent with the teaching of the specification. As a result, applicant believes that the outstanding Official Action fails to meet its burden in showing that claim 8 is not enabled by the present disclosure.

Claim 6 was rejected under 35 USC §102(b) as allegedly being anticipated by BIRKETT et al. This rejection is respectfully traversed.

Claim 6 discloses a nucleic acid that hybridizes specifically under stringent conditions to a nucleic acid according to claim 4. BIRKETT et al. disclose "random priming" with a mixed oligonucleotide kit. The oligomers according to BIRKETT et al. include all possible combinations of nucleotide-hexamers. However, BIRKETT et al. use "random hexamers" and random priming and labeling procedures where one must rely on relatively low annealing temperatures. These procedures would

fall outside of the scope of the "stringent conditions" recited in claim 6.

Indeed, one of ordinary skill in the art would understand that the word "stringent" would not be connected to the buffers and temperature conditions that are used at reactions with hexamers. As a result, applicant believes that BIRKETT et al. fail to anticipate or render obvious the claimed invention.

Claims 14-15 were rejected under 35 USC §102(e) as allegedly being anticipated by HSU. This rejection is respectfully traversed.

Claims 14-15 relate to a method for screening proteins or protein analogues that resemble at least a part of the structure of the protein according to claim 1. However, HSU discloses screening of analogues for the capacity to mimic the activity of a CAIP-like polypeptide. CAIP proteins are not related to the proteins of the present application. Indeed, the CAIP proteins disclosed by HSU are quite different the proteins of the application. As a result, applicant believes that HSU fails to anticipate or render obvious the claimed invention.

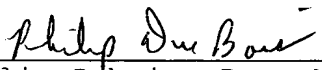
In view of the present amendment and the foregoing remarks, therefore, it is believed that the present application is now in condition for allowance. Passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional
fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON


Philip Dubois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/lk